UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 13, 2011

MEMORANDUM:

Subject: EPA Reg. No. 1022-522 / Cunapsol-5
DP Barcode: 387176
Case No.: 3099

From: Bentley C. Gregg, Biologist **[sign. B.C. Gregg & 2nd M. Perry]**
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

To: Maia Tatinclaux, CRM
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

Applicant: IBC Manufacturing Company
416 East Brooks Road
Memphis, TN 38109

FORMULATION FROM EPA Reg. No. 1022-522 LABEL:

	% by wt.
Active Ingredient(s):	
Copper Naphthenate *: ……..……..….....	45.4% [1]
Inert Ingredient(s): ….....	54.6%
Total	100.0%

(* Equivalent to 5% metallic copper) [1]

Contains Petroleum Distillates

[1] These data are from the revised draft label and the CSF, as well as from OPPIN Query (data which agree with the existing labels in PPLS, the two "Accepted" labels, dated 27-JUL-2004 and 11-JAN-1999, and "Notifications", dated 03-AUG-2010, 20-JAN-1021, and 08-APR-2004); however, RMIB V is currently conducting Product Chemistry reviews for the Copper Naphthenate products, and the data specified on the recent submissions might need to be revised. [This is a Product Chemistry issue and does not affect this acute toxicity review, and this clarifying note is only presented in this acute toxicity review for completeness for purposes of product reregistration].

BACKGROUND: In their 8 month response to the Product-specific Data Call-In [PDCI] for the AD RED from September 2007 for Copper and Zinc Naphthenates (with the Copper as OPP Chemical Code 023102), the registrant is citing some previously submitted acute toxicity studies and submitting a new study, and agreeing to Toxicity Category I resulting in restrictive labeling, to support the reregistration of their subject product, EPA Reg. No. 1022-522. The MRIDs cited are 429715-01 (81-1), 483851-03 (81-2), 449642-01 (81-3), and 429715-03 (81-6), with the 81-4 and 81-5 marked on their Data Matrix with a Note 2, and on another page, indicating "Note 2: Study not conducted. Tox Category I assumed based on pH." All these studies were conducted with EPA Reg. No. 1022-522, Cunapsol-5, the subject product. (Note that in a review dated April 6, 1987, by F-HB / RD, concerning the subject product and its MRIDs, primary dermal irritation (81-5) study and a primary eye irritation study (81-4) [both by Bio/dynamics, Inc., Project No. 5462-84 for dermal, and 5463-84 for eye] had been reviewed, and found to be Toxicity Category "I" for each study, confirming the registrant request to not cite and/or submit studies for these acute toxicity guidelines).

The oral (81-1) and dermal sensitization studies (81-6) had both been conducted by Stillmeadow, Inc., and had both been reviewed and found to be acceptable in an RSB / RD review, dated 11/17/93 (along with an inhalation study, 429715-02 in that same series of MRIDs, a study with an LC_{50} of 0.44 mg/L, so Toxicity Category "II").

This Tox Category II inhalation study had been the subject of two PSB / AD reviews, dated August 10, 2000, and January 25, 2002, in the former review, the registrant had been questioned regarding the formulation tested, and why a new MRID was then-submitted (the one now cited by the registrant, 449642-01), but in the latter of these two AD reviews, the reviewer resolved that the registrant has made formulation changes [("Alternate Formulation (VOC Formula)" would now be the "Basic" CSF], and that the testing in the new MRID (449642-01) had been conducted utilizing a use-dilution, and that the newly cited inhalation MRID was found to be acceptable, as follows:

Table: acute toxicity regulatory profile for Cunapsol-5, new 09/12/1996 formulation

Data Requirement	Means of Support	Status
Acute Oral Toxicity	MRID 429715-01 (Reviewed in 01/24/1994 agency memo)	Tox Category III
Acute Dermal Toxicity	Waiver (Reviewed in 01/24/1994 agency memo)	Waived
Acute Inhalation Toxicity	MRID 449642-01 (Reviewed in 01/24/1994 agency memo)	Tox Category IV
Eye Irritation	Accession No. 266172 (Reviewed in 04/06/1987 agency memo)	Tox Category I
Skin Irritation	Accession No. 266172 (Reviewed in 04/06/1987 agency memo)	Tox Category I
Skin Sensitization	MRID 429715-03 (Reviewed in 01/24/1994 agency memo)	Sensitizer

This table corroborates the registrant request for citation for the MRIDs for 81-1 and 81-6, and this table also accepts the 04/06/1987 Toxicity Categories for 81-4 and 81-5, based on MRIDs therein cited, although it is noted that the registrant is now citing the pH of the product in order to accept a "Toxicity Category I" determination for those tests. While the above table references a 1994 memo for the acceptance of the cited inhalation study, that study was not completed until 1999, and our searching of Agency records indicates that no review can be located. Thus, this newly cited inhalation study (449642-01) is reviewed herein, and found to be acceptable for 81-3. Dermal toxicity had been waived in the table from the AD 2002 (above), but, inexplicably, the registrant has now submitted a new study (483851-03), which is reviewed herein, and found to be acceptable.

Thus, while there are multiple sources of data, the currently cited, submitted, and requested-to-be waived studies are all found to be mutually consistent with previous submissions, and thus, the registrant data and studies, all for their subject product, are found to be acceptable herein.

RECOMMENDATIONS:

- The acute toxicity studies cited for 81-1 and 81-6 are acceptable, having been conducted with the subject product, EPA Reg. No. 1022-522.
- The registrant request to accept a Toxicity Category "I" for 81-4 and 81-5 is herein accepted.
- A review for the formerly submitted acute inhalation study (81-3) could not be located, and it is reviewed herein, and found to be acceptable, based on a formulation change and AD decision concerning use-dilution testing.
- The newly submitted study for 81-2 is reviewed herein, and found to be acceptable.

The acute toxicity profile for EPA Reg. No. 1022-522 is currently:

Acute Oral	III	Cited (LD_{50}: F: 1180 mg/kg; Comb. 1240 mg/kg; M: 1400 mg/kg)
Acute Dermal	III	Cited (LD_{50} > 2000 mg/kg & < 5,000mg/kg for females & males)
Acute Inhalation	IV	Cited (LC_{50} > 6.85 mg/L ["wet-weight"]; 0/5 females; 0/5 males)
Primary Eye	I	Cited
Primary Dermal	I	Cited
Skin Sensitization	Sensitizer	Cited

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:
ID #: 001022-00522 Cunapsol-5 [WOOD PRESERVATIVE]
[The words in brackets above appear on the revised draft label]

SIGNAL WORD: DANGER

RESTRICTED USE CLASSIFICATION:

The criteria for Restricted Use Classification are met due to the eye irritation and dermal irritation results.

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Corrosive. Causes irreversible eye damage. Cause skin burns. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes, on skin, or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear goggles or face shield. Wear coveralls over long-sleeved shirt and long pants, socks and chemical-resistant footwear, and chemical-resistant gloves (such as those made from any water-proof material [Selection Category A *).

(* If Selection Category A for gloves do not provide adequate protection for this product, the registrant should indicate a specific glove category from the EPA chemical resistance chart that will provide adequate protection.)

FIRST AID:

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Immediately call poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give **any** liquid to the person. Do not give anything by mouth to an unconscious person. (This statement is included herein because of the presence of petroleum distillates.)

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The proposed label must contain the following guidance:

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the Primary Dermal Irritation Toxicity Category I. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

DATA REVIEW FOR ACUTE DERMAL TOXICITY (§81-1, 870.1200)

Product Manager: Jacqueline Campbell-McFarlane **Reviewer**: Bentley C. Gregg
MRID No.: 483851-03 **Study Completion Date**: December 13, 2010
Report No.: 30700

Testing Facility: Eurofins PSL
Author: Carolyn Lowe

Quality Assurance (40 CFR §160.12): Included

Test Material: Cunapsol-5, Batch #: 100804-001, Dark blue-green liquid/faint ammonia like odor

Species: Sprague-Dawley derived albino rat

Conclusion:

1. **LD_{50} (mg/kg):** > 2,000 mg/kg and < 5,000 mg/kg

2. **Toxicity Category:** III **Classification**: Acceptable

Procedure (Deviations from §81-1): none

Results:

Dose mg/kg	(number deaths/number tested)		
	Males	Females	Combined
2,000	0/5	0/5	0/10
5,000	5/5 *	5/5	10/10

* 2/5 males were euthanized for humane reasons and are considered as mortalities.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: Jacqueline Campbell-McFarlane **Reviewer**: Bentley C. Gregg
MRID No.: 449642-01 **Study Completion Date**: 10th September 1999
Report No.: RIA 010

Testing Facility: Huntingdon Life Sciences Ltd.
Author: Graham R. Paul

Quality Assurance (40 CFR §160.12): Included

Test Material: A blue liquid identified as Cunapsol 5 (ICC 207-2C)

Species: Sprague-Dawley derived albino rat

Summary:

1. **LC_{50} (mg/L):** **> 6.85 mg/L**

2. **MMAD:** 2.4 µm **GSD:** 2.56

3. **Tox. Category:** IV **Classification**: Acceptable

Procedure (Deviation From §81-3): none

Results: **Reported Mortality**

There were no deaths following exposure of rats to a droplet aerosol, generated from a 1:2 dilution (v/v) of Cunapsol 5 (ICC 207-2C) in distilled water, at a concentration ('dry solids') of 0.53 mg/l in air. The achieved concentration of total droplets ('wet-weight') was 6.85 mg/l.

Exposure Concentration	(number deaths/number tested)		
	Males	Females	combined
4.5 mg/L	5/5	5/5	10/10

TABLE 1

Chamber concentration of Cunapsol 5 (ICC 207-2C)

Gravimetric analysis

Group	Sample identity	Time taken (h:min)	Chamber concentration (mg/l)		Proportion of 'dry solids' in total droplets (%)	Nominal concentration [c] (mg/l)
			Total droplets	'Dry solids'		
2	[1]	-0:50	10.46	0.57	5.4	
(Test)	[2] [a]	-0:24	8.96	0.53	5.9	
	3	0:10	7.33	0.53	7.2	
	4	1:01	6.88	0.57	8.3	
	5 [b]	2:02	7.15	0.52	7.3	
	6	3:00	6.28	0.50	8.0	
	7	3:46	6.63	0.53	8.0	
		Mean	6.85	0.53	7.8	41.6
		sd	0.417	0.025	0.48	

sd Standard deviation

[ ] Sample excluded from calculation of mean, obtained to confirm chamber concentration prior to exposure of rats

[a] Test substance feed rate decreased to 0.80 ml/min at -0h:30 min

[b] Chamber concentration (Sample 4) high, chamber exhaust airflow checked and found to be low. Exhaust airflow re-calibrated

[c] Calculated from the total amount of diluted test formulation dispersed by the generator (249.3 g) and the total volume of air (6000 litres) supplied to the exposure system during generation ('run-up' and exposure of rats)

TABLE 2

Droplet size distribution of Cunapsol 5 (ICC 207-2C)

Gravimetric analysis of 'dry solids'

Group	Sample	Time taken (h:min)	Stage	Cut-off size (µm)	Amount collected (mg)
2 (Test)	PSD 1	1:25	3	9.80	0.09
			4	6.00	0.24
			5	3.50	0.14
			6	1.55	0.33
			7	0.93	0.12
			8	0.52	0.14
			Filter	0.00	0.00
				Total	1.06
	PSD 2	3:25	3	9.80	0.00
			4	6.00	0.10
			5	3.50	0.11
			6	1.55	0.32
			7	0.93	0.13
			8	0.52	0.11
			Filter	0.00	0.10
				Total	0.87

Calculations

Cut-off size (μm)	% less than size (cumulative)
9.80	95.5
6.00	77.9
3.50	64.9
1.55	31.2
0.93	18.2
0.52	5.2
MMAD (µm)	2.4
σg	2.56
% respirable (<7 µm)	87

MMAD Mass median aerodynamic diameter

σg Standard geometric deviation